

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2005/001398

International filing date (day/month/year)
09.05.2005

Priority date (day/month/year)
18.05.2004

International Patent Classification (IPC) or both national classification and IPC
A61J3/07, B65B1/38, B65B1/48

Applicant
I.M.A. INDUSTRIA MACCHINE AUTOMATICHE S.P.A.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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IAP20 Rec'd PCT/PTO 16 FEB 2006

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	7,8
	No: Claims	1-6
Inventive step (IS)	Yes: Claims	
	No: Claims	1-8
Industrial applicability (IA)	Yes: Claims	1-8
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1 Reference is made to the following documents:

D1: WO 00/32474 A (I.M.A. INDUSTRIA MACCHINE AUTOMATICHE S.P.A; TREBBI, ROBERTO) 8 June 2000 (2000-06-08)

D2: US 2001/035431 A1 (RUNFT WERNER) 1 November 2001 (2001-11-01)

D3: DE 43 36 233 A1 (ROBERT BOSCH GMBH, 70469 STUTTGART, DE) 27 April 1995 (1995-04-27)

2 The present application does not meet the criteria of Article 33(1) PCT,

2.1 The document D1 (pages 5 - 9, fig. 1 - 8) discloses (the references in parentheses applying to this document):

A capsule filling machine for the production of hard gelatin capsules (C) comprising a lid (C1) a body (C2) containing a quantity of pharmaceutical material, the machine comprising a rotary turret or carousel (14) which defines at least one capsule (C) handling line (F) and on which the following are positioned, one after the other, one station (K11) for feeding empty capsules (C), one opening station (K12) where the capsule bodies (C2) are separated from the lids (C1) to form two separate rows of capsule bodies (C2) and lids (C1), one station (K1 - K5) for feeding and dosing the quantities (Q1-Q4) of pharmaceutical material to be filled into the capsule bodies (C2) and one station (K7) for closing the capsules (C) by placing a lid (C1) over each respective body (C2), the machine being characterised in that it further comprises means for detecting and volumetrically checking the quantity (Q1-Q4) of pharmaceutical material filled into each capsule body (C2), the detecting and checking means comprising transducer means (T, T') for measuring the volume of said quantities (Q1-Q4) before they are inserted into the capsule bodies (C2)

Document D2 discloses also a capsule filling machine with all the technical features of claim 1.

- Therefore, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
- 2.2 Claim 6 claims the method for using the machine claimed in claim 1. As D1 discloses a machine including all the technical features of claim 1, the method for using it is also disclosed in this document. Therefore, the subject-matter of claim 6 is also not new in the sense of Article 33(2) PCT.
- 2.3 Dependent claims 2 to 5, 7 and 8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

Novelty:

D1; pages 5 - 9, fig. 1 - 8; for claims 2 to 5

Inventive step:

D3; column 3, lines 41 - 58, fig. 1; for claim 7

The feature "linear transducer" is merely one of several straightforward possibilities from which the skilled person would select without the exercise of inventive skill, in order to measure the height of the pharmaceutical material inside the chamber. LVDTs (Linear Variable Differential Transformer) are often used to detect and transmit physical position of mechanical parts via electrical signals. Therefore claim 8 does not involve an inventive step.

Re Item VII

Certain defects in the international application

- 3 Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 4 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art

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disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.